April 20, 1999

Dockets Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, MD 20852

Dear Sir or Madam:

I am writing in reference to Docket No. 98P-0504, the petition from Center for Science in the Public Interest concerning molluscan shellfish.

The Jamestown S'Klallam Tribe has a treaty protected right to harvest shellfish. We have a substantial clam fishery which is of significant economic importance to the Tribe. In addition, for the past ten years we have owned and operated a commercial oyster farm. We have a great deal at stake in addressing the petition.

We vigorously support the appropriate regulation of shellfish harvest and handling to insure the protection of public health. We have been actively involved in the Pacific Rim Shellfish Sanitation Program for fourteen years, we operate a HACCP approved shellfish processing plant, and of course follow all NSSP protocols. As you may be aware, we co-manage the National Shellfish Sanitation Program with the State of Washington and other Treaty Tribes, as a result of the Consent Decree.

However, we strenuously object to several aspects of the petition from the Center for Science in the Public Interest. Among them:

- The presumption of "guilty until we prove ourselves innocent" if ever a product perhaps from Washington State is "implicated" in an illness.
- The suggestion of imposing a proprietary processing method (Ameripur) as a public health regulation.

Both aspects fly in the face of the good government and the democratic process. In addition we question the "science' and the good sense behind the petition:

The use of "non-detectable level" as a regulatory tool.

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- The presumption that controls which may be needed to manage vibrio vulnificus are appropriate for other vibrios.
- The request to put controls in place while research is under way by FDA and while interim control measures are successfully being implemented, at least here in Washington State.

JAMESTOWN S'KLALLAM

For all these reasons we urge that you dismiss the above petition and instead diligently pursue appropriate methods for dealing with vibrio vulnificus to protect public health.

Sincerely,

W. Ron Allen, Chairman Jamestown S'Klallam Tribe

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